

**In Re:**

*Digitek*

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*Paul Galea*

*December 9, 2009*

*Confidential – Subject to Further Confidentiality Review*

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*GOLKOW TECHNOLOGIES, INC.*

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Paul Galea

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

- - -

IN RE: DIGITEK® PRODUCTS MDL NO. 1968  
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO  
ALL CASES

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- - -

Wednesday, December 9, 2009

- - -

Videotaped deposition of PAUL  
GALEA, held at HARRIS BEACH, PLLC, 100 Wall  
Street, New York, New York, commencing at  
approximately 9:50 a.m., before Rosemary  
Locklear, a Registered Professional Reporter,  
Certified Realtime Reporter, Certified Court  
Reporter (NJ) and Notary Public.

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WITNESS

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By Mr. Blizzard

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56	2-page copy of document dated 5/16/07 entitled "Interoffice Memorandum," ACTAV000378817	100
57	3-page copy of document entitled "2007 Complaint Report," ACTAV000335330	110
58	1-page copy of E-mail dated 5/29/07 to Scott Talbot from Paul Galea, ACTAV000342737	117
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1 noise on the phone, I just want to let you know  
2 ahead of time that I will stop and have that  
3 person identify themselves.

4 A. That's fine.

5 Q. Sir, we met just a moment ago,  
6 but would you please state your full name.

7 A. Paul Galea.

8 Q. Yes, sir.

9 And where are you currently  
10 employed?

11 A. Actavis Totowa, L.L.C.

12 Q. And when were you first hired  
13 by Actavis?

14 A. By Actavis Totowa, L.L.C., or  
15 Actavis as a group?

16 Q. Let's go Actavis as a group.

17 A. Actavis became an entity in  
18 2004, I believe, so I guess it's around  
19 about that time.

20 Q. And then when would you  
21 identify that you no longer worked for  
22 Actavis Group, but you now became an  
23 employee of Actavis Totowa, L.L.C.?

24 A. I still believe that I work as

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1 an employee of Actavis in general.

2 Q. Okay. So my understanding,  
3 then, is, you don't consider yourself an  
4 employee of Actavis Totowa, L.L.C., you  
5 consider yourself an employee of Actavis  
6 Group.

7 A. I'm being paid by Actavis  
8 Totowa, L.L.C., so I guess that would make  
9 -- make me a current employee of Actavis  
10 Totowa, L.L.C.

11 Q. Okay. So then, prior to 2004,  
12 you were paid by Actavis Group?

13 A. Actavis, Limited, which is a  
14 subsidiary of Actavis Group.

15 Q. I'll just tell you, I'd like to  
16 go over a couple of rules before we go any  
17 further.

18 Have you been deposed before in the  
19 past?

20 A. No.

21 Q. I'm going to be asking a series  
22 of questions, and if I ask a question and  
23 you don't understand it, would you ask me  
24 to rephrase the question?

1           A.     If I remember correctly, around  
2     about that time I was validation officer,  
3     and then within the same year I moved into  
4     the role of assistant QA manager.

5           Q.     Is it fair to say that as a  
6     validation officer, you have come out of  
7     the manufacturing role and gone back into  
8     the world of QA?

9           A.     That can be termed as correct.

10          Q.     And what are you validating as  
11     a validation officer?

12          A.     As a validation officer, there  
13     were various projects going on, so I was  
14     taking care of cleaning validation and  
15     facilities, our -- and equipment  
16     validation.

17          Q.     And that was at the Actavis  
18     Totowa plant.

19          A.     No. That has still been Malta  
20     at Actavis, Limited.

21          Q.     Okay. What year did you  
22     transfer from Malta to Actavis Totowa  
23     physically?

24          A.     21st October, 2007.

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1 Q. Was that at the request of the  
2 company or had you been requesting to  
3 transfer to the U.S.?

4 A. It -- it was a bit of both, I  
5 could say.

6 Q. What was -- as you were  
7 informed, what was the reason that the  
8 company requested it, that you transfer to  
9 Actavis Totowa?

10 A. The initial reason, I was doing  
11 an assessment and helping out in the  
12 harmonization of the group's corporate  
13 manual, and that was basically the main  
14 reason.

15 Q. All right. Well, let's break  
16 that into two parts.

17 What was the assessment that you  
18 believe that you were -- that you came here to  
19 work on? Assessment of what?

20 A. Basically, I came to make an  
21 assessment of Actavis Totowa, L.L.C.

22 Q. Overall assessment of the QA  
23 Department?

24 A. No. In general of the company

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1 from a -- from a GMP perspective.

2 Q. Would you agree with me that  
3 there was some serious GMP issues in  
4 October of '07 at Actavis Totowa?

5 MR. ANDERTON: Objection.

6 You may answer.

7 THE WITNESS: How do you define  
8 serious?

9 BY MR. MILLER:

10 Q. Serious? Well, there could  
11 have been some GMP problems that would  
12 have been, gosh, this is minor, we either  
13 need to fix it or we don't need to fix it,  
14 or there are some issues where if we don't  
15 fix it, then we might be shut down or  
16 someone might get hurt.

17 MR. ANDERTON: Objection.

18 BY MR. MILLER:

19 Q. It's okay to answer.

20 MR. ANDERTON: You may answer.

21 THE WITNESS: When I first went  
22 there, that was not really the scope of my  
23 assessment. My assessment was to look at the  
24 company and -- and, basically, have a look at

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1 assessment of GMP at Actavis Totowa?

2 A. I was there for initial  
3 assessment, which was around a week, and  
4 then there were subsequent visits to do  
5 further assessments.

6 Q. Did your assessment include  
7 actual inspection and review of the  
8 quality-control labs within Actavis?

9 MR. ANDERTON: Objection.

10 You may answer.

11 THE WITNESS: Yes.

12 BY MR. MILLER:

13 Q. What all did you physically  
14 review or inspect in order to make an  
15 assessment of the GMP systems in Actavis?

16 MR. ANDERTON: Objection.

17 I'm going to instruct the witness  
18 to answer, but not to reveal any of the findings  
19 or evaluations or substantive evaluations that  
20 you did.

21 You may answer his question, but in  
22 answering don't reveal any of your conclusions  
23 or findings.

24 THE WITNESS: The assessment was

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1 more of a general assessment, which -- which is  
2 -- which you would typically do when you're  
3 visiting for a short period of time.

4 BY MR. MILLER:

5 Q. So you went inside the QA lab.

6 MR. ANDERTON: Objection.

7 BY MR. MILLER:

8 Q. You can answer.

9 A. QC lab.

10 Q. I'm sorry. So you went inside  
11 the QC lab.

12 Did you interview any lab techs  
13 there?

14 A. Not really.

15 Q. No?

16 A. Not really.

17 Q. What does not really mean?

18 A. I didn't interview anyone.

19 Q. Okay. Did you review lab  
20 analysts' logbooks?

21 MR. ANDERTON: Objection.

22 I instruct the witness not to  
23 answer.

24 I mean, you're getting into the

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1           A.     No. No. That is incorrect.  
2     What I am saying is, my initial assessment  
3     was February 2nd, 2007, until February  
4     9th, around about, 2007.

5           Q.     Okay. Well, I'm sorry. I  
6     thought you originally arrived 25 October  
7     of 2007.

8           A.     No. My answer to your question  
9     was, I started as an employee to Actavis  
10    Totowa on the 21st of October 2007. My  
11    first visit was in February of 2007.

12          Q.     And that visit was for roughly  
13    a week.

14          A.     Around about.

15          Q.     And was that strictly for  
16    assessment or was that for the  
17    harmonization of the company as well?

18          A.     It was for the assessment.

19          Q.     Assessment.

20                 Did you make any other visits to  
21    Totowa prior to you permanently coming here in  
22    21 October of 2007?

23          A.     Yes, I did.

24          Q.     And when were the other visits?

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1           A.     Roughly, I can say that one was  
2     in March.

3           Q.     Of '07.

4           A.     Of '07.

5                     I believe one was around about the  
6     end of May, another visit was around about June  
7     to July, and I believe the final visit was  
8     sometime in August.

9           Q.     And were each of these as well  
10    for the purpose of assessment of the GMP  
11    program?

12          A.     Not really. The initial visit  
13    was more of an assessment. Subsequently,  
14    it was also more to look at harmonization.

15          Q.     So the March visit you agree  
16    was assessment and harmonization?

17          A.     Yeah. They -- they rolled over  
18    into each other, more or less.

19          Q.     Okay. And you say that's true  
20    for all, the March, the May, the June and  
21    the August?

22          A.     I wouldn't say assessments. I  
23    would say more leaning towards  
24    harmonization.

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1 Q. Do you recall when that report  
2 was?

3 A. Probably sometime in -- after  
4 the February visit.

5 Q. And would you have sent that to  
6 Mr. Talbot?

7 A. No.

8 Q. You sent that directly to  
9 Mrs. -- I guess her first name is Gudrun;  
10 is that right?

11 A. I probably sent it to the QSD  
12 department. It's the quality systems  
13 department, which takes care of internal  
14 audits for the group.

15 Q. And if you would have E-mailed  
16 that report, would it have been an  
17 attachment to the QSD?

18 A. Typically, yes.

19 Q. And who specifically would you  
20 have written that report to? Do you  
21 recall?

22 A. Specifically, I cannot recall  
23 to whom.

24 Q. Would it have been who was in

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1 the report that would have been done for QSD  
2 after the February visit, or is there some other  
3 report?

4 A. It's the same report.

5 Q. So after your -- you did an  
6 assessment in March of 2007 and didn't  
7 report any information to anyone? You  
8 kept it all to yourself?

9 A. No. I did an assessment in  
10 February and my -- that was my initial  
11 report.

12 Q. You did an initial report after  
13 your February visit?

14 A. Yes.

15 Q. Okay. But you came back and in  
16 March you did a second visit that you said  
17 was part assessment, part harmonization?

18 A. Yes.

19 Q. After that trip, did you share  
20 any information with anyone or did you  
21 harbor it all to yourself?

22 A. Going forward from the second  
23 trip onwards, I was mainly in the  
24 harmonization state and looking, you know,

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1 at the various procedures, so I didn't  
2 really have any more things to report.  
3 But I was actually working on procedures.

4 Q. Okay. So is it fair to say  
5 that in March, May, June and August all  
6 four of those visits, there was some  
7 portion of it was assessment, but it was  
8 only for yourself. You weren't sharing  
9 any information with anyone else?

10 A. Not really. I would say the  
11 assessment ended around about March.

12 Q. Okay. But part of March was an  
13 assessment?

14 MR. ANDERTON: Objection.

15 You may answer.

16 THE WITNESS: I can recall that as  
17 being, you know, the tailing end of the initial  
18 assessment.

19 BY MR. MILLER:

20 Q. Okay. That tailing end, did  
21 you share any of the information you  
22 obtained in the tailing end of the  
23 assessment in the March visit with anyone?

24 A. Not that I recall.

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1 and not about other drugs, and you're  
2 instructing the witness not to answer questions  
3 clearly about GMPs that also apply to the  
4 manufacture of Digitek.

5 MR. ANDERTON: I'm instructing the  
6 witness not to answer the substance of an  
7 analysis that falls under a privilege protecting  
8 that information.

9 MR. BLIZZARD: I've never heard of  
10 the privilege before, but perhaps you'll  
11 enlighten us later.

12 MR. ANDERTON: Ready, Mr. Miller?

13 MR. MILLER: I am ready.

14 BY MR. MILLER:

15 Q. Now I want to talk to your  
16 second function and your trips in 2007 to  
17 Actavis Totowa.

18 Harmonization. Explain what that  
19 means to you. What was your goal there?

20 A. Okay. As the word is a bit of  
21 a fancy word, but, basically, a  
22 harmonization is to look at the various  
23 companies and see that they are working  
24 under the same umbrella.

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1                   When you have a big corporation,  
2                   it's something that you typically would like to  
3                   do.

4                   Q.       And are you harmonizing the GMP  
5                   aspect of the company or was it more  
6                   broad?

7                   A.       GMP aspect.

8                   Q.       Okay. So you're still working  
9                   with looking at GMP at Actavis Totowa, but  
10                  it's gone from an assessment to a how can  
11                  you work better with the rest of the  
12                  company?

13                  A.       I would say it's more how to  
14                  streamline operations within the various  
15                  countries to look as similar as possible.

16                  Q.       Under -- wearing your  
17                  harmonization hat in your visits March  
18                  through August, who did you report to?

19                  A.       Gudrun on those visits.

20                  Q.       Did you generate any reports  
21                  following those four visits to Gudrun?

22                  A.       No.

23                  Q.       All your communication with her  
24                  would have been over the phone.

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1 Q. Okay. Now, you're not from the  
2 United States, you're from Malta; correct?

3 A. Yes.

4 Q. And had you ever -- had you  
5 visited the United States before February  
6 of 2007?

7 A. No.

8 Q. And what was your job before  
9 you came to the United States for Actavis?

10 A. I was QA manager at Actavis,  
11 Limited.

12 Q. And Actavis, Limited, was their  
13 headquarters in Malta?

14 A. It is a subsidiary of the  
15 headquarters in Iceland.

16 Q. Okay. So the group that you  
17 worked for in Malta was a subsidiary of  
18 the headquarters of Actavis, which is  
19 located in Iceland; right?

20 A. That is correct.

21 Q. And you were the QA manager?

22 A. Yes.

23 Q. And was there anybody in the  
24 Malta operation that you reported to in

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1 practices?

2 MR. ANDERTON: Objection.

3 You may answer.

4 THE WITNESS: There's a long list.

5 BY MR. BLIZZARD:

6 Q. Okay. I'm not asking you to  
7 list them. I'm asking you to generally  
8 describe so that the jury understands what  
9 they are. What are good manufacturing  
10 practices?

11 A. Okay. They're a set of rules  
12 and guidances which direct you in the  
13 manufacturing and packaging and testing of  
14 your product.

15 Q. And what is the purpose of  
16 these rules and guidances?

17 MR. ANDERTON: Objection; asked and  
18 answered.

19 You may answer.

20 THE WITNESS: The objective is to  
21 manufacture a tablet which is good for human  
22 use.

23 BY MR. BLIZZARD:

24 Q. Okay. So is it part of the

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1 good manufacturing practices to assure  
2 safety?

3 A. Yes.

4 Q. Is it also part of good  
5 manufacturing practices to assure that the  
6 pills have the appropriate identity,  
7 strength and quality and purity?

8 MR. ANDERTON: Objection.

9 You may answer.

10 THE WITNESS: Yes.

11 BY MR. BLIZZARD:

12 Q. Is it the standard of care  
13 within the manufacturing of  
14 pharmaceuticals industry to follow good  
15 manufacturing practices?

16 MR. ANDERTON: Objection.

17 You may answer.

18 THE WITNESS: Yes.

19 BY MR. BLIZZARD:

20 Q. And if a company fails to  
21 follow good manufacturing practices, is it  
22 in violation of the standard of care?

23 MR. ANDERTON: Objection.

24 You may answer.

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1 full-time employee of Actavis Totowa in  
2 October of 2007; correct?

3 A. Yes.

4 Q. Before that you were employed  
5 by a separate corporation called Actavis,  
6 Limited; correct?

7 A. Yes.

8 Q. And it was only after October  
9 of 2007 that you came indirectly involved  
10 with the Quality Systems Improvement Plan;  
11 correct?

12 A. Yes.

13 Q. And what was your indirect  
14 involvement?

15 A. The Quality Systems Improvement  
16 Plan as it stands is to create actions for  
17 improvement or -- or tasks. So I was  
18 given tasks on occasion which my  
19 department had to fulfill.

20 Q. Have you ever heard of the  
21 phrase "if it ain't broke, don't fix it"?

22 A. In America, I've heard that.

23 Q. Okay. So was there -- was the  
24 quality system broken before this Quality

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1 Q. Right.

2 But it means the same thing as a  
3 corrective action plan; correct?

4 A. Yes.

5 Q. And both a corrective action  
6 plan and a quality -- Quality Systems  
7 Improvement Plan, both are intended to  
8 address deficiencies in the quality  
9 department, are they not?

10 A. No, that is not correct.

11 Q. Okay. They're both intended to  
12 address deficiencies in the company;  
13 correct?

14 MR. ANDERTON: Objection.

15 THE WITNESS: That is not correct.

16 BY MR. BLIZZARD:

17 Q. Okay. So are corrective action  
18 plans part of the routine business of the  
19 company?

20 A. Yes.

21 Q. And is it also a routine part  
22 of the company business to do assessments  
23 of the company's compliance with GMPs?

24 A. Yes.

Paul Galea

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CERTIFICATE

I HEREBY CERTIFY that the witness  
was duly sworn by me and that the deposition is  
a true record of the testimony given by the  
witness.

It was requested before completion  
of the deposition that the witness, PAUL GALEA,  
have the opportunity to read and sign the  
deposition transcript.



-----  
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